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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,535	12/21/2001	Tony Marcel	P07479US01/BAS	2128

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EXAMINER	
WEGERT, SANDRA L	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/024,535	MARCEL ET AL.	
	Examiner	Art Unit	
	Sandra Wegert	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-50* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The Restriction requirement of 13 July 2004 was reviewed by the examiner. Claims 23-36 were inadvertently omitted from that Office Action. Upon further consideration, the Restriction requirement is hereby VACATED. A new Restriction requirement follows:

Elections/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-20 and 22, drawn to a method of treating a disease by administering a ligand, classified in class 514, subclass 2+.

II. Claims 21 and 22, drawn to a method of treating a disease by administering two ligands that act synergistically, classified in class 530, subclass 300+.

III. Claims 23-36, drawn to a composition comprising an SMR1 peptide, classified in class 530, subclass 300+.

IV. Claim 37-50, drawn to a method of preparing a medicament, classified in class 530, subclass 333+.

Furthermore, under 35 U.S.C. 121, restriction to a single invention is required, from the following:

a) an avoidance disorder,

b) a decreased awareness disorder,

c) an autistic disorder,

d) schizophrenia,

e) an attention deficit/hyperactivity disorder,

f) an arousal disorder,

g) hospitalism,

h) decreased interest in the environment,

i) impaired interpersonal functioning,

j) impaired relationship to the external world,

k) schizoid personality disorder,

l) a depressive disorder,

m) schizophrenia,

n) a mood disorder

o) impaired social activity linked to sexuality,

p) untimely ejaculation,

q) hypoactive sexual desire disorder,

r) simple phobia,

s) social phobia,

t) obsessive-compulsive disorder,

u) acute stress disorder, or

v) a mental disorder related to a pain disorder,

Furthermore, under 35 U.S.C. 121, restriction to a single invention is required, from the following:

a) SEQ ID NO: 1,

b) SEQ ID NO: 2,

c) SEQ ID NO: 3,

d) SEQ ID NO: 4,

e) SEQ ID NO: 5,

f) SEQ ID NO: 6,

g) SEQ ID NO: 7,

h) SEQ ID NO: 8,

i) SEQ ID NO: 9, or

j) SEQ ID NO: 10.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventive Groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons:

The methods of Inventions I, II and IV are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals. A method of treating a subject is different depending on the subject's disorder because the disorders have different underlying etiologies and therefore require different treatment protocols. Each disorder requires different treating personnel and different drugs, equipment, and diagnostic tools.

In addition, a method of treating a disease with compounds that act synergistically has different underlying etiologies than a method that requires one compound. A method of preparing a medicament uses quite different equipment and personnel than a method of treatment and, likewise, uses different marterials and steps.

Inventions I and II are related to Invention III as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05 (h)). In the instant case the polypeptide of Group III can be used to generate antibodies as well as used therapeutically.

Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide can be prepared or extracted from a variety of sources and can be used in a variety of compositions.

Furthermore, Each disorder (a) – (v) represents a patentably distinct inventive Group. Groups (a) through (v) are independent and distinct, each from the other, because they have different underlying etiologies, different treating personnel, different diagnostic criteria, and require completely different search terms, starting points and strategies.

Furthermore, each set of sequences (a) – (j) represents a patentably distinct invention. Groups (a) through (j) are independent and distinct, each from the other,

because they have different putative functions, different structures, and require completely different search algorithms, starting points and strategies.

Because these inventions are distinct for the reasons given above and the search required for each group is unique, and because disorder and each peptide requires a completely separate search, as well as by their divergent subject matter and different search requirements, restriction for examination purposes as indicated is proper.

In response to this requirement, applicants must elect from Inventions I, II or III, and must additionally elect a *disorder* and a polypeptide *sequence*. Applicant is advised that in order for the reply to this requirement to be complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(i).

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW

19 July, 2004

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER